DOCUMENT MODIFICATION REQUEST (DMR)

Refer to 1-A01-PPG-001 for Processing Instructions.
Print or Type All Information (Except Signatures)

1. Date	25.
10/11/93	DMR. No. 93-DMR- 000908

2. Existing Document Number/Revision	3. New Document Number or Document Number if it is to be changed with this Revision
3-21000-ADM-12.01, Rev. 0	2-~~1~~6-ER-ADM-12.01
4. Originator's Name/Phone/Page/Location	**5. Document Title**
Rotha Randall/6910/NA/080-147	Control of Measuring and Test Equipment

6. Document Type ■ Procedure ☐ Other _____

7. Document Modification Type (Check only one)
☐ New ☒ Revision ☐ Intent Change ☐ Nonintent Change ☐ Editorial Correction ☐ Cancellation

8. Item	9. Page	10. Step	11. Proposed Modifications
NA	NA	NA	This procedure describes the manner in which measuring and test equipment (M&TE) are controlled for quality. M&TE are controlled in order to provide equipment and instrument performance within a known and acceptable range. Control of M&TE is achieved through calibrations, measurements, inspections, and testing.

12. Justification (Reason for Modification, EJO#, TP#, etc.)

This procedure is required to implement the Quality Assurance Project Plan.

If modification is for a new procedure or a revision, list concurring disciplines in Block 13, and enter N/A in Blocks 14 and 15. If modification is for any type of change or a cancellation, organizations are listed in Block 13, then Concurrer prints, and signs in Block 14, and dates in Block 15.

13. Organization	14. Print and Sign (if applicable)	15. Date (if applicable)
EQS	NA	NA
FOM	NA	NA
RPM	NA	NA
EE&T	NA	NA
SPP	NA	NA
GEO	NA	NA
SAA	NA	NA
	Required Reading	

16. Originator's Supervisor (print/sign/date)
Mark Brooks Mark C. Brooks 10/14/93

17. Assigned SME/Phone/Page/Location	18. Cost Center	19. Charge Number	20. Requested Completion Date	21. Effective Date
Jeff Caldwell/7181/4011/T891E	~~NA~~ 0248 10/1/93 K.T.	~~NA~~ 12/1/93 K.T. ER-ADM	01/31/94	~~NA~~ ~~5/5/95~~ 5/12/95

22. Accelerated Review?	23. ORC Review
Yes ☐ No ■	Not Required

24. Responsible Manager (print, sign, date)
Mark C. Brooks

RtC for final distribution on 5/1/95

REVIEWED FOR CLASSIFICATION/UCNI
BY NA
DATE NA

856D0094.DMR

ADMIN RECORD

A-SW-002331

DISCIPLINE-SPECIFIC CONVENTION FORM

Date: 3/14/93

During Comment Resolution of Procedure 2-G16-ER-ADM-12.01, the following discipline-specific conventions have been identified See Environmental Restoration Management Procedure Implementation Plan and Memorandum of Understanding with Plant Procedure Group (RFP/ER-MP-93IP.001). This document addresses general changes applicable to all Environmental Restoration Management procedures.

A request for an exception for all ERM Level 2, 3, & 4 procedures was granted 12/23/93 and includes all changes identified in RFP/ER-MP-93IP.001.

Check the origin of this modification:

☐	Internal Review Comment	☐	Writer Issue
☐	SubORC Comment	☒	Adopted Convention
☐	ORC Comment	☒	DOE Comment
☐	New Issue	☐	Building Management
☐	RCRA	☐	OSHA
☒	IAG/CERCLA/RCRA	☒	ERM QAPjP (IAG Document)

This convention affects all groups for the following series of procedures:
ERM Level 2, 3 and 4 procedures and any ERM Level 1 procedure related to IAG activities. Note, the only convention affecting ERM Level 1 procedures relates to required additions to the title page.

Completed by:

Rotha Randall	Rotha Randall	03/14/94
Print	Signature	Date

Instructions:

1. Writer or Editor records date, procedure number, and the convention identified for modification.
2. Writer or Editor checks (✓) origin of the modification.
3. Writer or Editor indicates the group affected by the modification and documents modification.
4. Writer or Editor distributes form to affected groups and Editors.

INFORMATION ONLY

ROCKY FLATS ENVIRONMENTAL TECHNOLOGY SITE	Manual No.:	2-11000-ER-ADM (a.k.a. 3-21000-ADM)
	Procedure No.:	Table of Contents, Rev 35
ERPD ADMINISTRATIVE	Page:	1 of 3
PROCEDURES MANUAL	Effective Date:	05/12/95
CATEGORY 1	Organization:	Environmental Restoration

TABLE OF CONTENTS FOR ENVIRONMENTAL RESTORATION PROGRAM DIVISION ADMINISTRATIVE PROCEDURES MANUAL

DOCUMENT CLASSIFICATION REVIEW WAIVER
PER R.B. HOFFMAN, CLASSIFICATION OFFICE
JUNE 11, 1991

Rocky Flats Environmental Technology Site

INFORMATION ONLY

2-G16-ER-ADM-12.01

REVISION 1

CONTROL OF MEASURING AND TEST EQUIPMENT

APPROVED BY: S.G. Stiger / S.G. Stiger / 4-11-95
Director, Environmental Restoration Program Division — Print Name — Date

Mark C. Brooks For / MARK Brooks / 4/7/95
Quality Assurance Manager, Data Management and Reporting Services — Print Name — Date

DOE RFFO/ER Concurrence on file: ☐ Yes ☐ No ☑ NA

Environmental Protection Agency Approval Received: ☐ Yes ☐ No ☑ NA

Responsible Organization: Environmental Restoration Program Division Effective Date: 5/12/95

CONCURRENCE BY THE FOLLOWING DISCIPLINES IS DOCUMENTED IN THE PROCEDURE HISTORY FILE:

Data Management and Reporting Services
Environmental Operations Management
Environmental Quality Support
Metrology
Solar Pond Projects
Performance Assurance

USE CATEGORY 4

ORC review not required

The following have been incorporated in this revision:
93-DMR-000908

This procedure supersedes 3-21000-ADM-12.01, Revision 0.

Periodic review frequency: 1 year from the effective date

LIST OF EFFECTIVE PAGES

Pages	Effective Date	Change Number
1-24	5/12/95	93-DMR-000908

TOTAL NUMBER OF PAGES: 24

TABLE OF CONTENTS

1. PURPOSE

This procedure establishes the control and calibration of the Environmental Restoration Program Division (ERPD) measuring and test equipment (M&TE) consistent with Rocky Flats Environmental Technology Site (Site) requirements and the Environmental Protection Agency (EPA) requirements as set forth in the Quality Assurance Project Plan (QAPjP). This procedure implements the requirements of Procedure 1-I97-ADM-12.01, Control of Measuring and Test Equipment.

2. SCOPE

This procedure applies to process monitoring and data collection M&TE (including contractor and subcontractor M&TE) used to make measurements or to calibrate devices used to make measurements as specified in the ERPD operating procedures.

Contractors and subcontractors may use their own M&TE procedures provided they are approved by the ERPD Operations Manager (OM), Project Manager, and Quality Assurance Manager (QAM) or Quality Coordinator. All Department of Energy (DOE) owned M&TE which requires calibration is calibrated by Rocky Flats Metrology. Contractor provided M&TE must be calibrated by an approved facility. All contractor M&TE calibrations must be traceable to the National Institute for Standards and Technology (NIST).

Section 5.4 does not apply to calibrations performed by Metrology or other Rocky Flats calibrating organizations that calibrate M&TE for use by the ERPD. These other organizations must comply with the requirements established by 1-I97-ADM-12.01.

This procedure addresses the control of the M&TE that does not require calibration to ensure that it is clearly identified and used appropriately.

This procedure addresses the following topics:

- Identification of M&TE
- M&TE General Related Activities
- ERPD Onsite Calibration
- Offsite M&TE Calibration and/or Maintenance
- Ensuring Conformance
- Controls
- QA Records Handling

This revision is a total rewrite and revision bars are omitted. This revision supersedes 3-21000-ADM-12.01.

3. DEFINITIONS

Accuracy. The closeness of a measured value to the true or standard value.

Accuracy and operability checks. Field verification that the M&TE is operating within acceptable norms by checking its performance against a known source. Operability verifies that the instrument is functioning.

Bias. A systematic error that remains constant over a series of replicated measurements.

Calibrate Before Use. A category used for the M&TE that is inherently unstable and must be calibrated before measurement use.

Calibrating organization. An organization which is qualified to perform calibrations by utilizing traceable standards including:

- Adjustment or alignment of instruments as required.
- Certification of the calibrations performed.
- Provide standards which are traceable to the NIST or other recognized national standards.
- Records Maintenance.

Calibration. The comparison of a measurement standard or item of measuring and test equipment of unknown uncertainty to a standard or instrument of known uncertainty, better than the M&TE, in order to detect, correlate, report, or eliminate by adjustment, any variation (deviation) in the uncertainty of the item being compared.

Calibration Certificate. This certificate is provided by a non-Rocky Flats source which calibrates the M&TE. This certificate documents and certifies the uncertainty/tolerance, calibration interval, and traceability to the NIST or other nationally approved standards. See Step 5.4[4] for minimum content for this certificate.

Calibration Interval. The period of time that the M&TE is expected to perform within assigned uncertainty/tolerance.

Calibration Not Required. A category which excludes certain M&TE from calibration based on the intended measurement use of such equipment.

Calibration Status. M&TE that is Active, Calibrate Before Use, Calibration Not Required, Inactive, or etc.

Control of Measuring and Test Equipment. Activities, systems, subsystems, or mechanisms both physical and administrative that when implemented, demonstrate with objective evidence compliance with this procedure.

Independent Reviewer. An independent observer trained in the specific technical field who reviews the operations or proposed plans of another organization or group.

3. DEFINITIONS (continued)

Measuring and Test Equipment (M&TE). All measuring instruments, measurement standards, and auxiliary apparatus that are necessary to perform a measurement. This includes measuring equipment used in the course of testing and inspection as well as used in calibration.

Precision. Describes the dispersion of repeated measurements.

Quality-Affecting Measurement. Any measurement required to ensure the protection of health, safety, and the environment or to demonstrate regulatory compliance.

Requirements. Administrative and technical actions or processes that essentially control the M&TE.

Standard. An artifact, instrument, system of instruments, or process established or recognized by an acknowledged authority by which one or more units or values of measure is defined, conserved, reproduced, or represented, in order to transmit or transfer them to other measurement instruments by comparison.

Tolerance. A specification for the amount of maximum allowable deviation from a standard. A tolerance may be derived from an engineering evaluation or the M&TE recalibration history.

Uncertainty. An estimate of the inability of a measurement process to measure the true value. Uncertainty encompasses both the equipment and process errors of the measurement process.

Unique Identifier. The Model Number and Serial Number of each item of the M&TE which is not calibrated or serviced by Metrology, or a unique control number assigned to each item of M&TE which is calibrated or serviced by Metrology.

User. A group which administratively controls and maintains a piece of the M&TE or standard and is accountable for its proper use.

User Calibration. Calibrations performed and documented by users of the M&TE prior to use. For example: functional and performance checks. (See Calibrate Before Use)

Calibration Variance Report. A generic term for a method that notifies the M&TE users of an out-of-calibration condition.

4. RESPONSIBILITIES

4.1 Director or Designee

Ensure that the M&TE is properly controlled, handled, and stored.

Ensure that the M&TE is properly selected and calibrated in accordance with this procedure.

4.2 Operations Manager (OM) or Designee

Acts as the M&TE Coordinator for the ERPD and consolidates the information provided by the ERPD management. This includes providing information to and interfacing with Metrology.

Ensures that the M&TE which is unreliable or fails to meet performance requirements is replaced.

4.3 Project Managers

Develop control procedures that identify the M&TE items, as needed.

Schedule calibrations for the M&TE that are consistent with ERPD procedures and Work Plans.

Specify the methods employed for personnel evaluation, training, and acceptance that are consistent with ERPD procedures and work plans.

Provide the information on control, identification, documentation, and records quality of the M&TE to the QAM or Quality Coordinator.

Provide the control and the maintenance of any standards that are possessed by their organizations.

Ensure that the responsibilities listed for Users (Section 4.8, Users) are implemented.

4.4 Quality Assurance Manager (QAM) or Quality Coordinator

Maintains sufficient expertise to establish the requirement for control of the M&TE which affects the measurements made in support of the ERPD quality-affecting activities.

Ensures, in conjunction with the applicable Subject-Matter Expert, that applicable quality-affecting specifications, instructions, and processes for control, calibration, storage, and use of the M&TE are contained in the approved procedures.

4.5 Responsible Managers

Ensure that all personnel, including subcontractors, are trained and qualified to perform the duties, tasks, and responsibilities described in this procedure.

Ensure that all the core and the ERPD-specific training has been completed and documented and that copies of all the documentation have been forwarded to the ERPD training files.

Ensure that the calibration history of equipment is properly recorded and maintained.

Ensure that predictive and preventive maintenance are established and implemented to maintain continuously acceptable M&TE.

4.6 Work Plan Developers

Ensure that the M&TE calibration data for field-calibrated M&TE is complete.

Review the M&TE documentation for the field-calibrated M&TE and the Calibration Certificates that are provided by the non-Rocky Flats sources, which calibrate the M&TE during or after completion of the calibration activity, to assure that the as-found conditions are within specification.

Verify that there is technical justification for assuming that calibrations apply to instruments as a whole.

Verify that the calibrations are consistent with the measurements that are planned for the projected environments.

Establish and maintain the calibration intervals.

4.7 Calibrators

Perform the calibrations and the performance testing in accordance with approved procedures.

Maintain the calibration and the performance testing documentation.

Document the environmental conditions at the time of calibration.

Ensure that the M&TE calibration data contains all of the proper information.

Label the M&TE with an appropriate calibration label.

Use the calibration adjustment seals appropriately.

4.7 Calibrators (continued)

Ensure that all the M&TE calibrations are consistent with the standards, applicable guidance, and requirements identified in the M&TE List.

Ensure that the calibrations, measurements, inspections, and testing occur at the required intervals.

Identify, document, and notify the responsible manager of any M&TE that is:

- Damaged
- Inappropriate for the intended use
- Lost
- Out-of-tolerance
- Overdue for calibration

Submit the completed data and records.

4.8 Users

Use certified standards and equipment.

Identify, document, and notify the responsible manager of any M&TE that is:

- Damaged
- Inappropriate for the intended use
- Lost
- Past the calibration expiration date
- Suspected to be out of calibration because of a broken calibration seal
- Suspected to be out-of-tolerance

Ensure that the M&TE that is identified as requiring calibration has a current calibration status prior to measurement use.

Document the date of usage, the calibrator's initials, and the unique identifier of the equipment in the records associated with the measurement activity.

5. INSTRUCTIONS

Throughout this procedure, the ERPD management and others perform activities associated with Metrology. In all cases, the ERPD communication and transmission of documents to Metrology is made through the Environmental Operations Manager or designee. This individual will be the ERPD single point of contact with Metrology. This individual will support the ERPD management in implementing its responsibilities.

5.1 Identification of M&TE

NOTE 1: *The requirements in Steps [1] through [4] are based on the needs and commitments identified in the ERPD Work Plans and procedures.*

NOTE 2: *Steps [1] through [4] may be completed in any order.*

NOTE 3: *The list of M&TE is an integral part of the Work Plan and is referred to as the M&TE List.*

Project Managers

[1] Provide a list to the Responsible Manager of all of the M&TE required to complete the activities within his/her area of responsibility.

NOTE: *The QAM or Quality Coordinator may provide assistance to identify applicable requirements for the M&TE calibration, maintenance, and accuracy and operability checks.*

[2] Ensure that the applicable requirements for the calibration of the equipment identified in Step [1] are identified in the Work Plans and/or the procedures and reflect input from the technical experts, EPA, CDPHE, and the DOE, RFFO.

[3] Include the applicable requirements for calibration of the equipment identified in Step [2] on the M&TE List.

NOTE: *Identification of the M&TE and the criteria for performance is based on the ERPD Work Plans and procedures. These documents contain the technical and quality requirements established by the technical experts within ERPD, EPA, CDPHE, and the DOE, RFFO.*

[4] Identify the required maintenance (including predictive and preventive programs), operability tests, and acceptable accuracy and precision required for the use of the M&TE identified in Step [1] based on documented requirements, and include these requirements on the M&TE List.

[A] Resolve any discrepancies with the responsible ERPD management or Metrology.

5.1 Identification of M&TE (continued)

[5] Submit the M&TE Lists to the responsible Program Manager either directly or as part of the Work Plan.

Program Managers or Designees

[6] **WHEN** an activity within their department is not covered by a Project Manager, **THEN** Complete the tasks in Steps [1] through [4] for the activity.

[7] Examine the M&TE Lists for adequacy and arrange for revisions as necessary.

[8] Submit the M&TE Lists to the QAM or Quality Coordinator and OM.

OM or Designee

[9] Consolidate the M&TE List for the ERPD with input from the QAM or Quality Coordinator, and monitor the status of the M&TE, which includes providing reports to the ERPD management on the M&TE status, to ensure that only current M&TE is used for the ERPD activities.

5.2 M&TE Related General Activities

Users

[1] Verify that a current calibration exists for any M&TE before using it to make quality-affecting measurements.

[2] Document the impact and resolution of the concerns listed below using the variance report (see Appendix 1, Sample Calibration Variance Report):

- Calibration expired while still in use
- Broken adjustment seal
- Out-of-tolerance observed during operation or recalibration
- Calibration organization not notified prior to the M&TE repair or modification
- Damaged M&TE
- Other conditions that may impact the validity of quality-affecting measurements

5.3 Qualifications and Training

Director or Designee

[1] Ensure that the ERPD managers and Environmental Quality Support technical staff have received documented training or briefings on the requirements of this procedure.

Program Managers or Designees

[2] Specify the methods employed for the training of personnel, consistent with the ERPD procedures and Work Plans.

Project Managers

[3] Ensure that Users have received documented training in the use of the M&TE required for the completion of their tasks

5.4 ERPD Onsite Calibration Program

Director or Designee

[1] Enforce a calibration program for the items on the M&TE List that are the responsibility of the ERPD.

Program Managers or Designees

[2] Ensure that the calibration program incorporates the following requirements:

[A] Identify the OM or designee as the person from whom calibration labels are obtained.

[B] Ensure that the number of the calibration label, log, or data sheet is documented on the calibration certificate issued by an offsite calibration organization.

[C] Ensure that copies of all calibration data sheets, offsite calibration certificates, or equivalent documentation are sent to Metrology.

[3] Ensure that calibration labeling information contains the following:

- The Unique Identifier of calibrated equipment
- The calibration date
- The initials of the individual performing the calibration
- The location of the calibration facility
- The calibration due date
- The calibrated functions and ranges with tolerances

This information may be documented in the blank line on the label.

- Any special application to which the calibration applies

5.4 ERPD Onsite Calibration Program (continued)

Calibrators

[4] Ensure that the M&TE calibration data for field-calibrated M&TE and the Calibration Certificates provided by non-Rocky Flats sources which calibrate M&TE include the following information, as applicable:

- Instrument description and Unique Identifier
- Identification of the traceable standard/source including the accuracy and precision (for example, standard error at 95 percent confidence level), expiration date of its calibration, and the information identified in items 1 and 2 for the standard/source
- Assigned or applicable range of the instrument and the calibration
- Description of the as-found condition of the M&TE, including accuracy and functional state
- The accuracy and uncertainty after calibration (for example, the calibrated value) when calibration is performed
- The environmental conditions under which the calibration was performed (for example, temperature)
- Special uses, limitations, or status when applicable
- Any supplementary data needed for accuracy and operability checks
- Date and time of the calibration
- Procedure used in the calibration
- Calibration interval and expiration date
- Name and initials of the individual(s) performing the calibration

[5] Ensure that calibration seals are placed on all adjustments or the access to such adjustments after the instrument is calibrated.

[A] Equipment requiring calibration before use is exempt from this requirement.

[6] Ensure that calibration is consistent with the technical guidance, and the requirements identified in the M&TE List.

[7] Ensure that the traceable certified standards are employed when calibrating, measuring, inspecting, or testing equipment.

[8] Ensure that the standards are documented for uncertainty, stability, range, and resolution, according to their intended use.

5.4 ERPD Onsite Calibration Program (continued)

[9] Identify and document deficient equipment for any of the concerns listed below in accordance with 1-P04-SCMP-16.00, Sitewide Commitments Management Process, using the SCMP Identification Form:

- Calibration expired while still in use
- Broken adjustment seal
- Out-of-tolerance observed during operation or recalibration
- Calibration organization not notified prior to the M&TE repair or modification
- Damaged M&TE
- Other conditions that may impact the validity of quality-affecting measurements

[A] Document the impact and resolutions in Section 4 - Additional Comments of the SCMP Identification Form.

Work Plan Developers

[10] Ensure that the M&TE calibration data for field-calibrated M&TE includes the following information, as applicable:

- Formal requirements for the notification (including temporary hold point) if the as-found conditions exceed the tolerances on the M&TE List
- Additional special tests which may be required to establish as-found conditions for out-of-specification equipment so calibration can only proceed after authorization from the QAM or Quality Coordinator and the OM based on the variance report
- Description of any maintenance performed as a result of the calibration (for example, the documentation of any parts replaced and the justification for substitution of any replacement parts)
- Location and date of installation at Rocky Flats, if any. Otherwise, indicate the fate of the M&TE (for example, field survey instrument controlled by ...)

[11] Review the M&TE documentation discussed in Step [4] during or after completion of the calibration activity to assure that the as-found conditions are within specification.

[12] **IF** the as-found conditions are outside acceptable specifications,
THEN issue a Calibration Variance Report (see Appendix 1).

NOTE: *Calibration of an entire system or instrument in its functional configuration is required. However, separate calibration of selected required parameters of an instrument is acceptable when circumstances demand it.*

[13] Verify that there is technical justification for assuming that the calibration would apply to the instrument as a whole.

5.4 ERPD Onsite Calibration Program (continued)

[14] Verify that the calibration is consistent with the planned measurement and the projected environment.

[15] Establish and maintain calibration intervals based upon the required uncertainty/tolerance, purpose, manufacturer's recommendations, recognized industry standards, usage factors, stability characteristics, and/or the calibration history of individual M&TE.

[A] Intervals may be shorter than one day but not exceed five years.

[16] Standards may be maintained by Metrology or the subcontractor's calibration organization.

Responsible Managers and/or OM

[17] Maintain a working file or log of each piece of the M&TE that documents its calibration history in accordance with the ERPD Records Management requirements.

[18] Maintain the data from the accuracy and the operability checks in the working file or log.

[19] Ensure that the equipment requiring daily (that is, equipment calibrated before use) calibration is labeled with the words "Calibrate Before Use."

[20] **IF** the subcontractor M&TE is used for less than the calibration period of the instrument,
THEN ensure that the subcontractor M&TE is calibrated for initial and final verification.

[21] Ensure that yearly reviews, based on the dates maintained in Steps 5.4[3] and 5.4[4] and other sources, are made to assess the M&TE's performance and reliability.

[22] Ensure that the M&TE which is unreliable or fails to meet performance requirements is replaced as soon as practicable.

Work Plan/Procedure Developers

[23] Ensure that use, handling, and storage conditions are consistent with the capabilities and limitations of the M&TE based on available technical data, experience, and the manufacturer's recommendations.

5.5 Offsite M&TE Calibration and/or Maintenance

Responsible Managers

[1] Ensure that the requirements for any offsite calibration meet the intent of the requirements in Section 5.4.

[2] Coordinate any offsite calibration with Metrology and obtain their concurrence with all offsite calibration procurements.

NOTE: *Vendor documentation provides mandated information but may be in a format typically used by the vendor.*

[3] Verify that the documentation identified in Section 5.4 is supplied by the vendors performing the calibration and/or the maintenance of the M&TE.

[4] Verify that the M&TE Calibration Certificates (provided for non-Rocky Flats calibrations) and the calibration and maintenance data includes information identified in Step 5.4[4].

[5] Provide copies of all the calibration documentation received from the offsite calibrator to Metrology and the QAM or Quality Coordinator.

[6] Arrange for the review of the calibration documentation for adequacy by a qualified technical individual, the QAM or Quality Coordinator, and Metrology.

Technical individual and QAM or Quality Coordinator

[7] Issue an Non Conformance Report (NCR) in accordance with 1-P04-SCMP-16.00 if a concern is identified.

5.6 Ensuring Conformance

Responsible Managers

[1] Establish out-of-tolerance criteria as part of the Work Plan and the procedure development process to ensure that measurements made by the M&TE and the measurement standards that are found to be out-of-tolerance do not adversely affect quality.

[2] **IF** the M&TE is not functioning or potentially malfunctioning,
THEN tag the equipment in accordance with 1-P04-SCMP-16.00 to indicate that it is out of calibration and segregate, where feasible, until it can be repaired, if necessary, and recalibrated.

[3] Notify the calibrating organization to restore lost or damaged calibration labels after verifying that the calibration is current, as long as it is done in compliance with the requirements of Section 5.4.

5.6 Ensuring Conformance (continued)

[4] Label equipment that is considered to be M&TE but does not require calibration as "calibration not required."

[5] Control all documentation that set criteria for or directs the M&TE activities in accordance with 3-21000-ADM-06.01, Document Control.

[6] Resolve all Variance Reports in accordance with the instruction on the report form, including obtaining the concurrence of an independent reviewer and the approval of the ERPD responsible management.

[7] Submit all completed Calibration Variance Reports to the OM and QAM or Quality Coordinator (in addition to the ERPD Project File Center).

QAM or Quality Coordinator

[8] Arrange for a surveillance or self-evaluation, in accordance with 3-21000-ADM-18.02, Surveillance, of the M&TE Program at least once each year.

[9] Ensure that procedures addressing the use of the M&TE include the following:

- Clear identification of the M&TE to be used
- A requirement for verification of the M&TE prior to usage
- Inclusion of any accuracy and operability checks
- Clear specification of the required accuracy of the measurement
- Specification of any applicable environmental limitations
- Documentation of the M&TE used including the unique identifier

[10] Solicit approval from Metrology for purchase requisitions and purchase orders for the M&TE services and for equipment that will be calibrated by the Rocky Flats organizations other than the ERPD.

[11] After calibrating equipment, seal the calibration adjustments.

5.7 Controls

Responsible Managers and Work Plan/Procedure developers

[1] Ensure that all the measurement standards are approved by Metrology or identified in the work Plan or procedure subject to direct DOE RFFO, EPA, or CDPHE review.

[2] Ensure that all measurement standards include assignment of permissible error and expiration date.

5.7 Controls (continued)

Responsible Managers and Work Plan/Procedure Developers (continued)

[3] Ensure that the following controls are implemented for the measurement standards and the M&TE that do not affect safety or release requirements:

- Storage, handling, and transportation is performed in a manner that does not adversely affect the calibration or proper operation of the equipment
- Testing is performed prior to shipment to ensure proper operation
- Testing prior to shipment is documented
- Testing is performed (see second bullet of this step) upon return to verify that the equipment is operable and calibrated, if feasible
- Testing upon return is documented

[4] Request approval for the new M&TE and deletion from the recall system of the old M&TE by Metrology.

[5] Ensure that procedures addressing the calibration of the M&TE contain the following:

- Precautions and limitations for the M&TE
- Identification of calibration standards to be used in the calibration
- Calibration instruction and documentation of performance
- Acceptance criteria for each range
- Verification review of the calibration documentation by a qualified individual who did not perform the calibration

5.8 QA Records Handling

User

[1] Whenever the M&TE is used in the implementation of ERPD activities, document the date of usage and the unique identifier of the M&TE in the records associated with the activity.

Responsible Managers

[2] Submit copies of the maintenance and operations manuals and calibration records for all new instruments to the ERPD Project File Center and the Metrology Laboratories upon receipt of the M&TE.

[3] Submit copies of existing manuals for the M&TE to the ERPD Project File Center and Metrology as soon as practicable.

[4] Send copies of all the onsite calibration records, not associated with equipment that is calibrated before use, to Metrology as soon as practicable.

[5] Notify the ERPD Project File Center to accumulate each year's records for each specific M&TE in a single records package.

5.8 QA Records Handling (continued)

Responsible Managers (continued)

[6] **IF** the M&TE may be used to make measurements associated with the IAG activities, **THEN** label all records "Administrative Record."

[7] Transmit records to the ERPD Project File Center.

6. RECORDS

Management of all records is consistent with 1-77000-RM-001, Records Management Guidance for Records Sources.

OM or Designee

Ensure that the original and one copy (as required) of the following quality-related records, as appropriate, are transmitted to the ERPD Project File Center in accordance with 2-G18-ER-ADM-17.01, Records Capture and Transmittal:

- M&TE Non Conformance Reports
- M&TE Calibration Variance Reports
- M&TE Calibration Data (logbook, data sheets ect...)
- SCMP Identification Form
- M&TE List
- Calibration Histories (as required)
- Maintenance and Operation Manual (as required)

Submission of record copies to the ERPD Project File Center satisfies the Administrative Records Requirements in accordance with 2-S65-ER-ADM-17.02, Administrative Record Document Identification and Transmittal.

There are no nonquality records generated by this procedure.

7. REFERENCES

QAPjP, Rocky Flats Plant Environmental Management Sitewide Quality Assurance Project Plan

Rocky Flats Interagency Agreement, 01/22/91

1-I97-ADM-12.01, Control of Measuring and Test Equipment

1-P04-SCMP-16.00, Sitewide Commitments Management Process

1-77000-RM-001, Records Management Guidance for Records Sources

7. REFERENCES (continued)

2-S65-ER-ADM-17.02, Administrative Record Document Identification and Transmittal

3-21000-ADM-06.01, Document Control

3-21000-ADM-18.02, Surveillance Activities

APPENDIX 1
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FORM 12.01-A1, CALIBRATION VARIANCE REPORT

Rocky Flats Environmental Technology Site *ENVIRONMENTAL MANAGEMENT DEPARTMENT*	**CALIBRATION VARIANCE REPORT**	**Form 12.01-A1 REVISION 1 Page 1 of 2**

Number VR-_____

IDENTIFIER SECTION:

Date: __/__/__ Location: (Bldg./Area) _____

Time: _____ AM PM Specific Location (such as Room, Column): _____

M&TE Type: _____

Unique Identifier: _____

User: _____ Organization: _____

Reviewer: _____ Organization: _____

CALIBRATION SECTION:

Equipment Status: _____ Calibration Expired _____ Broken Adjustment Seal

_____ Out of Tolerance _____ Calibration Organization Not Notified Prior to M&TE Repair or Modification

_____ Damaged _____ Other (explain in comments)

For out of tolerance results:

Tolerance: _____ As-Found Value: _____

Tolerance: _____ As-Found Value: _____

Contact QAM or Quality Coordinator and User Organization for special test instructions and summarize any on attached sheets.

Special tests required: _____ No _____ Yes

Calibration Status: _____ ACTIVE _____ INACTIVE

_____ DELETED FROM M&TE LISTING

_____ OTHER (explain in comments)

COMMENTS: _____

CALIBRATOR:

_____ _____

Print Name Print Supervisor's Name

_____ _____

Calibrator's Signature Supervisor's Signature

APPENDIX 1
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Rocky Flats Environmental Technology Site *ENVIRONMENTAL MANAGEMENT DEPARTMENT*	**CALIBRATION VARIANCE REPORT**	**Form 12.01-A1 REVISION 1 Page 2 of 2**

Number VR-_____

USER ORGANIZATION SECTION: Reply by: _____

Out of Calibration Impact Evaluation: _____

_____

_____

Disposition/Corrective Action Taken: _____

_____

_____

Impacts Data Quality or Safety: . . . . . ____ Impacts Data Validity: . . . . ____

Personnel Exposure Potentially Affected: . . . ____ NCR Generated: . . . . . ____

(If an NCR is generated specify the number: _____)

Comments: _____

_____

_____

_____ _____ _____

Print Name Evaluator (User Organization) Date

INDEPENDENT REVIEW SECTION:

Concurrence with impact evaluation: ____ No ____ Yes

If no explain: _____

_____

_____

_____ _____

Print Name Organization

_____ _____

Signature Date

MANAGEMENT CONCURRENCE/AUTHENTICATION:

_____ _____ ___/___/___

Manager of Responsible Organization Signature Date
Please Print

_____ _____ ___/___/___

ERPD Quality Assurance Manager Signature Date
Please Print

_____ _____ ___/___/___

ERPD Calibration Program Coordinator Signature Date
Please Print

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Instructions For Completion of Calibration Variance Report

1. Calibration Variance Report Number is designated by the OM or use "VR-MMDDYY-III-NN" where:

   a. MMDDYY is the date in that format,
   b. III is your initials, and
   c. NN is the number of Variance Reports issued that day.

2. Complete the initial block as indicated (Calibrator)

   a. "S/N" means serial number.
   b. Station refers to any assigned station for installed equipment.
   c. User, Reviewer, and Reviewer's organization need only be filled out if there are routine designees for these functions, otherwise enter "NA" for not available.

3. Complete the Calibration Section (Calibrator)

   a. Indicate why the Variance Report was prepared.
   b If an out-of-tolerance condition was found, include the tolerance values and the as-found values (if there are more than two values, attach additional sheets and note this in the comment section).
   c. Indicate if the QAM or Quality Coordinator or User Organization requires additional testing to establish data quality and attach any instruction to this form. Note the number of pages of instructions in the comment section.
   d. Complete the balance of this section.
   e. Record the "VR-" number for the other page of the form and indicate the date for reply by the user in the User Organization Section.

4. User organization completes the balance of the User Organization Section.

   a. The user documents the evaluation of the impact of this variance in the M&TE on the data generated using this equipment.
   b. The user identifies the applicable correction actions taken to ensure the quality of the data.

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Instructions For Completion of Calibration Variance Report (continued)

5. Contact Environmental and Waste Audits and Assurance which will designate an independent reviewer who is qualified to complete this evaluation. The independent reviewer will evaluate the impact and correction actions to be taken to determine their adequacy. Concurrence of the independent reviewer is required. Signature of the independent reviewer is required on the Variance Report.

6. The Independent Reviewer completes his/her section.

7. Designated individuals complete the Management Concurrence/Authentication section when they are satisfied with the accuracy of the conclusions of the Variance Report.

8. Send the Variance Report to the Responsible Manager, QAM or Quality Coordinator, Calibrator, Sample Management Manager, the Independent Reviewer, Rocky Flats Metrology Laboratories, and the ERPD Project File Center.